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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,318	05/31/2001	David Fikstad	WP 2001.00	1207

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/871,318

Applicant(s)

FIKSTAD ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5, 14 and 17-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5, 14 and 17-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Acknowledgment of Papers Received: Response dated 9/6/06.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 3-5, 14, 17-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Cormier et al (USPN 6,203,817 hereafter '817), and Ke et al (USPN 6,323,232 hereafter '232). The claims are drawn to a transdermal formulation comprising an adhesive drug matrix reservoir and lasofoxifene.

4. The '817 patent discloses a transdermal formulation comprising an adhesive drug matrix reservoir (abstract). The transdermal is attached to the skin and comprises a backing layer, adhesive overlay, and a release liner all sealed together to prevent leakage (col. 9, lin. 38-58). The formulation further comprises penetration enhancers (col. 10, lin. 5-56, examples). The transdermal formulation delivers various active agents including antiestrogen and

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antiosteoporotic agents such as tamoxifen and raloxifene (col. 7, lin. 66-68). The reference however lacks a disclosure of lasofoxifene a similar antiestrogen agent.

5. The '232 patent discloses a combination transdermal therapy including lasofoxifene and other estrogen agonists/antagonists (claim 1). Among other agents used in the combination therapy are droloxifene, raloxifene and tamoxifen (col. 6, lin. 35-40). A skilled artisan would have been motivated to include the lasofoxifene of '232 into the transdermal formulation of '817 in order to impart antiosteoporotic properties onto the formulation.

6. With these things in mind one of ordinary skill in the art would have been motivated to combine the teachings of '232 and '217 since both teach transdermal delivery of antiestrogen agents, in order to impart the antiosteoporotic properties of lasofoxifene onto the formulation. It would have been obvious to a skilled artisan to combine the teachings and suggestions with an expected result of transdermal device capable of treating various estrogen related disorders.

Response to Arguments

7. Applicant's arguments filed 9/6/06 have been fully considered but they are not persuasive. Applicant argues that:

- a. There is no motivation to include the lasofoxifene of the '232 patent into the formulation of the '817 patent since the compound is completely different from the apparent equivalent compounds.

Regarding this argument, it is the position of the Examiner that the artisan of ordinary skill would be motivated to include the lasofoxifene of the '232 due to its osteoporosis fighting properties. The '817 patent discloses a transdermal formulation comprising antiosteoporotic agents such as tamoxifen and raloxifene (col. 7, lin. 65-67). These compounds

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are well known for their antiosteoporotic properties as seen in the '232 patent (col. 6, lin. 3-40). Since each compound despite their difference in structure, solubility, etc. has well documented antiosteoporotic properties; a skilled artisan would be motivated to include the lasofoxifene of the '232 into the transdermal formulation in order to improve the antiosteoporotic properties of the dosage form. Applicant argues that the differences in structure would deter an artisan of ordinary skill from considering interchanging the lasofoxifene. The structural difference, along with others would be such that interchangeability would not be possible. However the Examiner relies on their shared antiosteoporotic property and the superiority of the lasofoxifene as the motivation to combine the teachings of the art. Applicant argues that the '232 provide no motivation regarding a reservoir or adhesive matrix. However the Examiner only relies upon the patent for its general teachings of treating low bone mass, transdermally with lasofoxifene, raloxifene and droloxifene.

For these reasons at least the claims remain obviated by the prior art combination.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

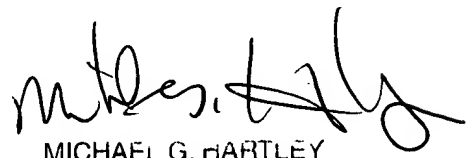
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618


MP Young


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER